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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,228	07/31/2003	Jaya Pathak	50623.251	1730

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EXAMINER

LIN, JAMES

ART UNIT	PAPER NUMBER
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1762

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07/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/631,228	Applicant(s) PATHAK ET AL.	
	Examiner Jimmy Lin	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14 and 16-34 is/are pending in the application.
 4a) Of the above claim(s) 7,11,12,14 and 19-22 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1,3-6,8-10,13,16-18 and 23-34 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/20/2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-6, 8-10, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. (U.S. Publication 2004/0063663), Inoue et al. (U.S. Patent 5,762,944), and Hughes et al. (U.S. Patent 5,756,659).

Claims 1,13: Buchanan discloses a method of making a carrier polymer that is used to coat the surface of a stent to provide controlled and sustained release of an anticoagulant drug at the preferred site [0065]. The coating can be formed by putting the carrier polymer along with the other additives into a twin screw extruder [0051]. The polymer can be a thermoplastic material [0059].

Buchanan does not teach 1) introducing a fluid into the extruder, 2) removing at least a volume of the fluid from the extruder such that an impurity is at least partially removed with the fluid, and 3) exposing the fluid to a temperature equal to or greater than the boiling temperature of the fluid at ambient pressure prior to removing the fluid from the mixing apparatus.

Inoue teaches a method of making a coating for a stent, wherein the coating comprises a polymer (col. 3, lines 1-31). Inoue recognizes the need to wash the polymer to remove impurities in the method of making medical devices such as a stent. The impurities can include a

solvent, an unreacted monomer, and an impurity (col. 6, lines 38-43). Hughes teaches a method of removing impurities, such as unreacted monomer, solvent, and thermally unstable species, from a molten polymer inside a twin-screw extruder. 1) A stripping agent is introduced into the polymer melt stream and the polymer/stripping agent mixture is homogenized in a mixing zone. 2) At least some of the stripping agent and impurities are removed from the polymer (col. 3, lines 10-33; Fig. 2). 3) The temperature of each extruder zone is controlled by a temperature controller and resistance heaters that are monitored by means of a series of thermocouples 29-36 (col. 3, lines 16-20). The temperatures of the thermocouples range from 112 to 240 °C (Table 6). Such temperatures are greater than the boiling temperature of a solvent, such as those taught in Inoue. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have introduced a fluid into the extruder to have removed impurities from the polymer of Buchanan because Inoue recognizes the need to remove impurities in a method of making a material for a medical device and because Hughes teaches that such an in-situ process is suitable in the art of removing impurities from a polymer. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

Claim 3: Buchanan teaches that a single screw extruder can also be used [0051].

Claim 4-5: Buchanan teaches that the polymer must be melted in the extruder [0051].

Claim 6: Inoue does not explicitly teach that the fluid is a type to physically entrap the impurity without dissolving the impurity. However, Buchanan does teach the use of thermoplastic polymers, while Inoue teaches that a thermoplastic polymer can be formed via a prepolymer (i.e., a monomer) processing method wherein the prepolymer is polymerized to form the thermoplastic polymer (Example 4). Such a polymerization technique would leave residual unreacted monomer (i.e., an impurity). Because formation of a thermoplastic polymer via a monomer polymerization technique is well known, it would have been obvious to one of ordinary skill in the art at the time of invention to have used such a technique to form the thermoplastic polymer of Buchanan and to have removed residual unreacted monomer using the method as taught in Inoue and Hughes with a reasonable expectation of success. At least some solvents as taught in Inoue (e.g., water) must necessarily physically entrap residual monomers.

Claim 8: Hughes teaches that a second stripping agent can be introduced to the extruder, wherein the stripping agent removes an impurity from the polymer (col. 3, lines 33-45).

Claim 9: Buchanan teaches that a suitable thermoplastic can be polyethylene-vinyl acetate copolymer (i.e., an ethylene-vinyl acetate copolymer) [0059].

Claim 10: Inoue teaches that a suitable solvent can be acetone (col. 6, lines 38-43).

Claim 31: Hughes does not explicitly teach that a solvent and a non-solvent are used as the first and second fluids, respectively, to remove an impurity. However, Hughes does teach that more than one fluid can be used to remove an impurity (col. 3, lines 23-38; col. 6, lines 26-28). The combination of references teaches a variety of suitable fluids to remove impurities. One of ordinary skill in the art would have used any combination of the suggested fluids, including a solvent and a non-solvent, with an expectation of similar results. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used any combination of solvents, including the use of a solvent together with a non-solvent, with a reasonable expectation of success because Hughes teaches that more than one fluid can be used.

Claims 32-33: Hughes teaches that the extruder temperature ranges from 112 to 240 °C. Such temperatures are greater than the boiling temperatures of the fluids.

4. Claims 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663, Inoue '944, and Hughes '659, as applied to claim 1, and further in view of Berg et al. (EP 0623354).

Buchanan, Inoue, and Hughes are discussed above, but do not explicitly teach that the polymer can be combined with a solvent. However, Berg teaches that a solution comprising a polymer and solvent can be applied to the coating of a stent and then evaporating the solvent (abstract). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have applied the polymer of Buchanan, Inoue, and Hughes in a solvent solution and then evaporating the solvent because Berg teaches that such a coating method is suitable in the art of coating a stent.

Claims 15-18 are rejected for substantially the same reasons as claims 2, 4-5, and 9-10 above.

5. Claims 23-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663, Inoue '944, and Hughes '659, as applied to claims 1 and 31, and further in view of Roorda et al. (U.S. Patent No. 2005/0106203).

Buchanan, Inoue, and Hughes are discussed above. Buchanan does not explicitly teach that the polymer can be poly(vinylidene fluoride-co-hexafluoropropene) or poly(butyl methacrylate). However, Buchanan does teach the use of thermoplastic polymers for making a coating medical device [0059], while Roorda teaches that poly(n-butyl methacrylate) is a suitable thermoplastic material for making a coating for an implantable medical device [0008]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used poly(n-butyl methacrylate) as the particular thermoplastic polymer of Buchanan with a reasonable expectation of success because Buchanan teaches that other thermoplastic polymers can be used and because Roorda teaches that such a polymer is suitable in the art. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

Response to Arguments

6. Applicant's arguments filed 4/20/2007 have been fully considered but they are not persuasive.

Claims 1-6 and 8-10 as rejected over Buchanan '663, Inoue '944, and Hughes '659:

The Applicant argues on pg. 9-10 that the combination of references fails to teach or suggest at what point of the process a solvent might be introduced. In particular, the Applicant argues that the references do not teach or suggest exposing a fluid to a temperature equal to or greater than the fluid boiling temperature at ambient pressure after the fluid has removed an impurity and prior to removing the fluid from a mixing apparatus. However, Hughes does teach that the extruder can be at a temperature ranging from 112 to 240 °C (Table 6). The fluid is injected into the extruder, to thereby expose the fluid to such temperatures. Additionally, the

Art Unit: 1762

fluid that is removed at the devolatilization zones would be vaporized easier with the addition of heat, especially at a temperature above its boiling point.

The Applicant argues on pg. 10 that using water for cleaning as disclosed in Inoue without knowing the type of impurity being removed would not necessarily physically entrap the impurity without dissolving the impurity. However, the rejection has been modified such that a solvent, such as water, is used to physically entrap residual monomer (i.e., a specific type of impurity).

Claims 13 and 15-18 as rejected over Buchanan '663, Inoue '944, Hughes '659, and Berg '354:

The Applicant argues on pg. 11 that the combination of references do not teach or suggest exposing a fluid to a temperature equal to or greater than the fluid boiling temperature at ambient pressure after the fluid has removed an impurity and prior to removing the fluid from a mixing apparatus. However, Hughes teaches such a limitation, as discussed above.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iguchi et al. (U.S. Patent 5,756,553) recognizes the need to remove impurities from polymers used for medical devices (col. 4, line 66 – col. 5, line 2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is 571-272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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TIMOTHY MEEKS
SUPERVISORY PATENT EXAMINER